Integrating Usability Into Development of a Clinical Decision Support System

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Abstract

Hospital leadership identified poor physician compliance with a patient treatment protocol that was intended to avoid the occurrence of blood clots in hospitalized patients. The computerized physician order entry (CPOE) system at that time was user driven; that is, no clinical decision support pathways were built into the system. Initial plans were to integrate a decision tree into the CPOE system, but leaders recognized that if physicians found the system to be cumbersome, they might refuse to use the system or develop workaround strategies. In order to minimize this possibility hospital leaders recognized a need for human factors engineering (HFE) input in the development of the system, but there was minimal funding and a short timeline allotted for this project. Through collaboration of a hospital physician having Human Factors knowledge and an external usability consultant, a successful pathway was added to the existing CPOE. The development of the pathway engaged relevant hospital personnel and utilized a special timesaving usability testing procedure. Implementation of the pathway resulted in improved physician compliance with the treatment protocol.

1. Background

The medical industry has been slow to integrate human factors engineering techniques into areas other than medical device design (Perry 2004). No studies have described the integration of human factors engineering (HFE) techniques into the CPOE development process (Chan 2002). This is possibly due, in part, to the lack of internal expertise (i.e. human factors engineers as members of the hospital staff) as well as to the lack of funding to engage external HFE consultants. Despite this, there is a need for HFE expertise in the medical environment, including usability techniques in the development of hospital computer applications (Welch 1998). In this paper, a patient-safety related problem and its potential IT solution are described, including the process which was utilized to optimize the ease of use of the system in order to increase the acceptance of the system among physicians.

2. Setting

This project was undertaken at the University of Rochester Medical Center, a 750-bed tertiary care, academic medical center and regional referral center that provides advanced oncology, transplant, cardiovascular, pediatric, geriatric, emergency, trauma, and other services. Physicians undergoing specialty training (residents) are responsible for placing the majority of orders for patients in this hospital, and they do so under the indirect supervision of senior attending physicians. All orders are entered into an existing computerized physician order entry (CPOE) system with a two-color display. The user interface is primarily character-based but includes rudimentary graphics in the form of buttons used to select options with the mouse.

3. Description of the problem

3.1 DVT/PE prophylaxis non-compliance among providers

The act of being hospitalized puts patients at risk for certain problems that are not directly related to the illness for which they have been hospitalized. Thromboembolism, including deep venous thrombosis (DVT) and pulmonary

embolism (PE), is one of the most common and dangerous of those complications (Baglin, White & Charles, 1997). Although PE is less common than DVT, it can lead to death. As a result, minimizing the occurrence of this complication is considered a high priority. Provision of prophylaxis (preventative treatment) to hospital inpatients dramatically reduces the risk of DVT/PE (Samama et al., 1999). But unfortunately physicians often fail to order appropriate DVT/PE prophylaxis for their patients.

3.2 Demonstration project funded by AHRQ via NYS DOH

In response to this problem, the New York State Department of Health funded the Rochester Regional Thromboembolism Collaborative with support from the Agency for Healthcare Research and Quality (AHRQ). This collaborative was charged with implementing interventions to improve compliance with recommended prophylaxis treatment, and to study the results of these interventions. Results were to be measured by level of compliance with the guideline.

The occurrence of thromboembolism can be reduced by providing hospitalized patients with prophylactic treatments which are selected based on the patient's risk category. As with many treatments in medicine, the balance between risks and benefits must be considered for each category of patient, so an evidence-based approach to prophylaxis is complicated. As a result, the hospital guideline used to guide clinicians to the right treatment is quite complex (Figure 1). Physician compliance with the guideline was generally poor. In our institution, compliance with this protocol was less than 50%, measured in terms of the proportion of high risk patients admitted to the hospital who received no effective prophylaxis. This low compliance rate was consistent with many other institutions.

3.3 Initial attempts at solution

In the early phases of the project, several interventions were used to improve compliance, including educating physicians, publicizing the importance of the guideline, utilizing nursing staff to provide reminders to physicians, placing the guideline prominently in the patient charts, and making follow-up phone calls to physicians who did not comply with the guideline. Though prophylaxis rates improved, these interventions failed to have the desired impact on the rate of correct prophylaxis orders. This was thought to be largely due to the complexity of the written guideline, which made it difficult and cumbersome for physicians to choose the appropriate therapy for each individual patient.

3.4 Attempt at CPOE-based solution

The research team, which was made up of hospital quality managers, physicians, nurses, and data managers, realized that building a compulsory pathway into the CPOE system (i.e., a forcing function) could be a valuable step towards increasing compliance. An initial prototype of the enhanced system was developed on paper, but the team realized that it would be quite cumbersome and time consuming for physicians, which could result in their resisting the program. Physicians often admit several patients to the hospital during a short time period and must spend a significant amount of time talking to the patient, conducting the examination, and reviewing the patient's medical record prior to entering orders. As a result, physicians usually have little time left to spend on order entry. Any change which adds time to this process or makes this process more difficult would result in strong resistance from physicians. This can result in failure of the system, either because of prevalence of work-around strategies or outright refusal to cooperate.

3.5. Research team invited HFE to join project

Recognizing the need for a physician-friendly system, the research team decided to bring a human factors engineer (HFE) into the project. Funds were limited so the team looked for internal resources, and turned to a hospital employee who is a physician with a master's degree in HFE.

3.6 Project goal

The overall objective was to convert the paper-based guideline to a computer-based algorithm and then implement it in a user interface (UI) that maximized ease of use. Specifically, the MD/HFE was charged with developing a decision pathway that guided the user to a recommendation for correct prophylaxis orders specific to each individual patient. This pathway had to be user friendly and non-encumbering to the physician user. The added pathway also had to conform to the existing character-based user interface.

4.0 UI development and implementation:

The overall process involved UI simulation, a form of iterative design testing called "progressive usability assessment (PUA)", purposive sampling to identify assessment participants, Beta testing, and rollout. Their integration into the development and implementation process is described in detail here.

4.1 Design activities

a) The MD/HFE investigator was integrated into the existing research team in order to know the players (investigators, developers, end-users), and help them better understand the problem.
b) The written patient treatment protocol was mapped to a logic diagram that represented cognitive decision process.
c) Using the PowerPoint software application with hyperlinks to make screen transitions, a simulation was created of the existing CPOE user interface with the decision process incorporated.
d) This PowerPoint simulation was examined by an external usability specialist who offered feedback and suggested modifications based on a heuristic review. The usability specialist did not possess domain knowledge. Modifications were made based on his feedback.
e) The simulation was presented to a team of domain experts, including subject matter experts, in order to verify medical accuracy (i.e. compliance with the written guideline). Modifications were made based on feedback from this session, which was conducted during a meeting of the research team.
f) The simulation was sent via email to the system programmers to verify feasibility of the design from a development perspective. Modifications were made based on feedback from their interaction with the simulation.

4.2 Testing and implementation

g) After the simulation had gone through the iterative design activities, it was presented to 22 end users in individual sessions. Participants (physicians in training) were recruited based on referrals from supervisors and peers. A purposive sampling technique was used; for example, physicians who had a history of particular resistance or difficulty with the existing CPOE system, those from specialties which use the system most often, and individuals who were expected to have a willingness to spend time to give thoughtful feedback, were sought out. Sessions were held at a time and location convenient to the physician-participants. The use of a laptop computer as the simulation platform added to the flexibility in location. The participants were asked to perform two tasks: place admission orders for two patients as they usually would, (1) one set for a low risk patient and (2) one for a high risk patient. Since these patients were imaginary, they were described to the participant before the simulation started. The participants were asked to think aloud, and the investigator asked further questions when participants encountered difficulty with the system. After the simulation, participants were asked to summarize their likes and dislikes, difficulties and successes with the system.
h) Detailed notes were taken during each session regarding successes and failures of the interface, user frustrations, and stumbling points, including potential sources of error. As soon as a trend was identified, appropriate modifications to the simulation were made and repeat testing was subsequently conducted. This continuous changing of the interface between participants, an iterative process, is an approach we call Progressive Usability Assessment (PUA) See the discussion section for more on PUA.
i) Once comments and feedback from all participants had been integrated into the simulation, the modified system was presented to the subject matter experts (medical content experts and system programmers) to ensure its accuracy and feasibility.

j) The HFE/MD then worked with the CPOE programmers to develop the system module based on the simulation.
k) A beta-test on the actual CPOE system was then conducted by enabling the module for approximately 10 volunteer physicians during a period of one week. These physicians were recruited because they were on a hospital team which would be doing frequent admission orders during the beta test period, and none of them had been participants in the PUA process. Daily feedback was solicited from these volunteers, and small refinements were ultimately made to the system based on their experiences.
l) The full system was then introduced hospital-wide. It was preceded by having one of the research team members visit physician staff meetings for most departments in the hospital and provide a 20 minute basic training session in the use of the new decision pathway. A developer/programmer and the HFE/MD were both on standby for the first 48 hours of the introduction to act as resources to the end user for problem-solving and to hear system feedback.

5. Results

During the educational sessions physicians were advised that the programmer and the MD/HFE would be available for the initial implementation period, and this message was repeated on the CIS logon screen during this 48-hour period. The support team received no calls for support during the period, despite the fact that the hospital experienced the typical volume of patient admissions.

As a result of this project, the hospital saw a dramatic increase in thromboembolism prophylaxis rates, from less than 50% at baseline, to 66% after paper guidelines were placed in patient charts and educational interventions were conducted, to 93% after introduction of the CPOE pathway. The nurse reminder and follow-up interventions continued, but were utilized much less often.

6. Discussion

6.1 Effectiveness of methodology

The process used in this study combined both traditional and unconventional methods. Design activities followed a typical course of understanding the problem, simulating a design solution, and involving others to verify the medical and technical soundness of the proposed solution. Beta testing and rollout were also typical of a sound process. The PUA was the main deviant from traditional methodology. The design used during the usability testing was not held constant as is typically done to allow data collected from the participants to be pooled together for analysis. Instead the design was changed frequently between participants as dictated by new findings. By the end of the testing little analysis remained to be done.

PUA represents an effective testing tradeoff for certain circumstances. Ideally, usability tests are iterated with a different set of participants after the user interface is redesigned based on previous test results. This consumes time and money to recruit and test new participant groups. When time and/or money are an issue, the PUA approach of incremental fixes can more quickly accomplish the testing. One requirement for the approach is the ability to readily make changes to the UI prototype. Paper and pencil prototypes allow quick changes to be made, as do certain software tools. In our case, PowerPoint proved to have great value as an inexpensive, easily modified simulation platform. Another requirement is a test administrator who is knowledgeable about the application domain so s/he can make educated judgments about when a finding seems valid enough to make another fix to the UI before continuing to run participants.

In actual practice, a planned traditional usability test can turn into a form of PUA. Often in traditional tests, some of the UI problems become clearly evident within the first few participants. The HFE may make prototype changes to accommodate the early findings and then continue with the rest of the test. The mid-course change is considered a normal part of the formal usability test and can go unreported. This is different than the planned PUA, which incorporates flexible participant scheduling to accommodate short intervals required to make incremental changes to the prototype.

When the situation permits, a combination of progressive usability assessment and traditional usability testing can be an especially effective process for arriving at a well-designed user interface. Running a traditional test after a PUA gives a verification of UI changes made and a final check for any new issues.

6.2. Summary

Since this was a high-profile initiative, the dramatic increase in compliance with the guidelines afforded through the enhanced CPOE system received a lot of attention by area hospitals and by the state health department. It was recognized that the success of this program was dependant on physician acceptance, and that the HFE involvement in the development of the process was likely to have had a large impact on that acceptance. This resulted in recognition of the value of HFE input by many hospital management and staff.

A sound development process was key to the successful outcome of the project. This included involving medical staff, developers and users at the appropriate times and avoiding overkill in the selection of a usability testing method. Having a physician on staff who understands and appreciates Human Factors was a significant advantage in this case and was a key factor in the hospital's decision to build usability into the UI design. However, since such physicians are rare, hospitals should be encouraged to send selected physicians to Human Factors short courses. This will help them recognize usability issues and to engage appropriate external resources if they cannot address the issues themselves.

7. References

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Figure 1: Hospital guideline used prior to the implementation of the CPOE pathway.

DVT-PE Risk Assessment & Prophylaxis (in Adults): Pattern

If orthopaedic (total hip or knee replacement, hip fracture), acute spinal cord injury, multiple trauma with risk factors, elective intracranial surgery or cesarean section, go directly to table 3, Procedure-specific Prophylaxis. For all other patients, review table 1 for risk factors and contraindications then consult table 2 for prophylaxis recommendations. In table 2, the surgical patient risk category is on the left, medical on the right; read the recommended prophylaxis in the middle column.

Table 1. Risk Factors and Relative Contraindications

Risk Factors

Major

- Prior DVT or PE
- Malignancy
- Hypercoagulable state, inherited or acquired
- Age > 60
- Prolonged immobility (>72 hrs) or paralysis
- Immobilizing cast
- Central venous access
- Myocardial infarction
- Heart failure, decompensated
- Sepsis or infection, severe
- Stroke, nonhemorrhagic

Minor

- Obesity (BMI 30 or greater)
- Heart failure, compensated
- Trauma
- Pregnancy or < 1 month postpartum
- Varicose veins
- Inflammatory bowel disease
- Oral contraceptive, hormonal replacement therapy, raloxifene (Evista), or tamoxifen (Nolvadex)

Contraindications for Inpatient Anticoagulant Prophylaxis*

- ***Active, uncontrollable bleeding***
- ***Cerebrovascular hemorrhage (not hx)***
- ***Dissecting or cerebral aneurysm***
- ***Bacterial endocarditis***
- ***Active peptic ulcer disease, ulcerative GI lesions (not hx)***
- ***Hypertension: severe, uncontrolled; malignant; hypertensive crisis***
- ***Severe head trauma***
- PT or PTT > 1.5 x control at baseline
- Hemorrhagic blood dyscrasias
- Threatened abortion
- Severe thrombocytopenia (platelet count < 30,000)
- Recent TURP (within several weeks)
- Eye, brain, or spinal cord surgery within the past 48 hrs.
- For **warfarin**: Pregnancy
- For **heparin, LMW heparins, heparinoids**: History of HIT

Contraindications for IPC

- Open wounds

Cautions

- Spinal anesthesia or manipulation of epidural catheters should be undertaken at the nadir of anticoagulant effect.

*more significant risks in ***bold italics***

Table 2. DVT-PE Risk & Prophylaxis

Surgical[a] Patient Risk Factors	Risk Class and Prophylaxis	Medical Patient Risk Factors
Minor[a] outpatient procedures	**Minimal** Continue ambulation	Ambulatory patient; nonsurgical procedure
Minor[a] surgery, age < 40, no risk factors	**Low** Early ambulation and leg exercises	Inpatient, no risk factors
Minor[a] surgery: • minor risk factor(s) • age 40-60, no risk factors Major[a] surgery, age < 40, no risk factors	**Moderate** **One** of: **Heparin 5,000 units SC q12h**[1] or LMWH[2,6] or GCS[3] or IPC[4] or IPC followed by heparin[7]	Inpatient, one minor risk factor
Major[a] surgery, age > 40 or risk factor(s) Minor[a] surgery, age > 60 Any surgery, major risk factor	**High** **One** of: **Heparin 5,000 units q8h**[1] or LMWH[5,6] or IPC[4] or IPC followed by heparin[7]	Myocardial infarction Stroke with lower extremity paralysis Patient with one major or two minor risk factors

[a]Major surgery > 45 min; minor surgery < 45 min.
[1]Surgical patients: first dose 1-2 hours preoperatively
[2]Surgical: Enoxaparin 20 mg SC, 1-2 hr preoperatively and once daily postoperatively or dalteparin 2,500 units SC, 1-2 hr preoperatively and once daily postoperatively
Medical: Enoxaparin 40 mg SC, once daily or dalteparin 2,500 units SC once daily
[3]Graduated Compression Stockings: must be individually measured; presized are TEDS, not GCS
[4]Intermittent pneumatic compression device if anticoagulation contraindicated or high risk for bleeding.
[5]Surgical: Enoxaparin 40 mg SC, 1-2 hr preoperatively and once daily postoperatively or dalteparin 5,000 units SC, 1-2 hr preoperatively and once daily postoperatively
Medical: Enoxaparin 40 mg SC, once daily or dalteparin 2,500 units SC once daily
[6]**Do not use LMWH or fondaparinux if spinal or epidural anesthesia is planned or possible; may cause surgery to be delayed or cancelled.**
[7]Intermittent pneumatic compression in the operating room and recovery room; then heparin 5,000 units SC just prior to transfer from the recovery room. If not fully ambulatory in 8-12 hours, continue heparin 5,000 units q12h (moderate risk) or q8h (high risk) until fully ambulatory.

Table 3. Procedure-specific Prophylaxis

Neurosurgery, elective intracranial	Intermittent pneumatic compression device
Acute spinal cord injury Multiple trauma, with any risk factor	Enoxaparin[3,4] 30 mg SC q12h
Orthopaedic surgery[1], e.g.: • total hip replacement	Adjusted-dose warfarin or enoxaparin[2,4] 30 mg SC q12h or 40 mg SC QD or dalteparin[2,4] 5,000 units SC QD or fondaparinux[4,5] 2.5 mg SC QD
• total knee replacement	Adjusted-dose warfarin or enoxaparin[2,4] 30 mg SC q12h or fondaparinux[4,5] 2.5 mg SC QD
• hip fracture	Adjusted-dose warfarin or enoxaparin[2,4] 30 mg SC q12h or 40 mg SC QD or fondaparinux[4,5] 2.5 mg SC QD
Cesarean section	Intermittent pneumatic compression in the operating room and recovery room; then heparin 5,000 units SC just prior to transfer from the recovery room. If not fully ambulatory in 8-12 hours, continue heparin 5,000 units q12h (moderate risk) or q8h (high risk) until fully ambulatory.

[1]Typically, initial therapy for 10-14 days then warfarin for an additional 4 weeks; target INR, 2 - 2.5
[2]Prophylaxis with a LMW heparin may begin 12 hrs prior to surgery but if not sufficient lead time should be held until 12 hrs after surgery.
[3]If patient requires surgery, restart LMW heparin 6 hrs postoperatively.
[4]**Do not use LMWH or fondaparinux if spinal or epidural anesthesia is planned or possible; may cause surgery to be delayed or cancelled.**
[5]Beginning 6-8 hours postoperatively.